DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 10, 2014

GEMSS Medical Systems Co., Ltd.
% Mr. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
HOUSTON TX 77071

Re: K132289
Trade/Device Name: Spinel 3G
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA, OXO
Dated: May 22, 2014
Received: May 23, 2014

Dear Mr. Knauss:

This letter corrects our substantially equivalent letter of June 16, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K132289

Device Name

Spinel 3G

Indications for Use *(Describe)*

The SPINEL 3G, Surgical Mobile Fluoroscopic X-ray system, is indicated for use in generating fluoroscopic / radioscopic images of human anatomy. This device is not intended for interventional guided procedure & mammographic applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Robert A Ochs

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May 22, 2014

1. Company and correspondent making the submission:

- Company Name: GEMSS MEDICAL SYSTEMS Co., LTD.
- Address : 61,Dunchon-daero 541(obaeksasibil), Jungwon-gu, Seongnam-si, yeonggi-do, Korea
- Telephone : +82-31-764-7321~3
- Fax: +82-31-764-7324
- Contact: Mr. Sangwoo Lee
- Internet: http://www.gemss-medical.com

2. General information for predicate & proposed device

	Predicate device	Proposed device
Manufacturer	United Radiology Systems, Inc.	GEMSS MEDICAL SYSTEMS Co., LTD.
510(k) number	K032761 (Decision Date - May. 14. 2004)	K132289
Common Name	Surgical Mobile Fluoroscopic X-ray System	Surgical Mobile Fluoroscopic X-ray System
Trade/proprietary name	KMC-950	SPINEL 3G
Classification rule	21CFR 892.1650	21CFR 892.1650
Classification Name	Image Intensified Fluroscopic X-ray System	Image Intensified Fluroscopic X-ray System
Product code	JAA & OXO & OWB	JAA & OXO

3. Description:

3.1 General:

The Image Intensified Fluroscopic X-ray System consists of a high voltage (HV) inverter generator, a tube support unit, an X-ray beam limiting device, mobile cart, a detector, operating software, and a tube, and is primarily used in a hospital for diagnosis of diseases in skeletal, respiratory and urinary systems such as the skull, spinal column, chest, abdomen, extremities, and other body parts. This device is not intended for interventional guided procedure & mammographic applications.

3.2 Product features:

The SPINEL 3G is a solution to produce radiological images of patient during medical operations. This inverter control X-ray unit visualizes the anatomical structure on screen, which is obtained by X-ray fluoroscopy and the image intensifier. This system can be applied in emergency room, operation room, cast room or etc. of hospital.

The SPINEL 3G has following features.

The high voltage generation circuit uses the method of inverter with a high power of 12kVA, to ensure that stable X-Ray with small amount of ripples are obtained.

The X-Ray tube system uses the X-Ray tube with rotating anode, thus enabling to obtain high-quality images necessary for the longtime operation or diagnosis.

Control panel adopting TACT key, B/W LCD and touch screen for excellent controllability and visibility.

Soft but solid motions of the large size C-Arm, which has a 768mm radius, gives facility to perform an operation.(Depth:692mm)

For fluoroscopy, the collimator is used to reduce an unnecessary irradiation of X-Ray.

Using the built-in SNAP SHOT mode, the image quality is improved further, and it has built-in DIS (Digital Interface System).

The SPINEL 3G has PACS connectivity with DICOM 3.0.

Thermal sensor prevents the tube from overheating. If the tube is overheated, thermal sensor attached to the exterior of it warns the system and 'Tube Limit' sign will be displayed on the touch screen. Then the machine can work again by the time the tube gets cooled.

4. Intended use

SPINEL 3G is intended to be used as a universal diagnostic imaging system and fluoroscopic studies. Using an Image intensifier and CCD camera, it can perform a range of applications including general fluoroscopy, diagnostic fluoroscopy. SPINEL 3G, Mobile Fluoroscopy System is designed to provide fluoroscopic of the patient during diagnostic, surgical procedures. Examples of clinical application may include horologic, orthopedic, neurologic, critical care and emergency room procedures.

5. Indications for use

The SPINEL 3G, Surgical Mobile Fluoroscopic X-ray system, is indicated for use in generating fluoroscopic / radioscopic images of human anatomy. This device is not intended for interventional guided procedure & mammographic applications.

6. Comparison with predicate device:

		Predicate device	**Proposed device**
Model name		KMC-950	SPINEL 3G
510(k) number		K032761	K132289
510(k) owner		United Radiology Systems, Inc.	GEMSS Medical Systems Co., Ltd.
X-ray Tube	Model name	Varian:RAD-99	Toshiba:E7833X, Varian:RAD-99
	Manufacturer	Varian	Toshiba/Varian
	Anode Type	Rotating	Rotating
	Heat Capacity	300,000 HU	300,000HU

		Predicate device	Proposed device
	Anode heat cooling	15kHU/min	15kHU/min
	Focal Size	0.3 mm / 0.6 mm	0.3 mm / 0.6 mm
X-ray Generator	Model name	HTC-120	HTC-120
	Manufacturer	POSKOM	POSKOM
	X-ray Generator Type	High frequency / inverter type	High frequency / inverter type
	Power Output	12.0 kVA	12.0 kVA
Fluoroscopic Mode	kV range	40 to 125 kV See below different discussion	40 to 120 kV See below different discussion
	mA range	0.5 to 5 mA See below different discussion	0.2 to 10 mA See below different discussion
	Pulse Fluoro	Yes	Yes
	ABS function	Yes	Yes
	Snap Shot	8.0 mA shot available	8.0 mA shot available
	Boost Shot	20.0 mA sot available	20.0 mA shot available
Image Intensifier	Model name	Thales:TH9428HP2	Toshiba:E5830SD-P4A, Thales:TH9438QX
	Manufacturer	Thales	Toshiba/Thales
	Size	9″	9″
	Magnification	9″ / 6" / 4.5″	9″ / 6" / 4.5″
Camera	Model name	RS-138EDR	LUNA-1K
	Manufacturer	RAYSIS	GEMSS Medical Systems Co., Ltd.
	Type	1/2" CCD	1/2" CCD
	active pixel	512X512	1024X1024
C-arm	Manufacturer	COMED Medical Systems Co., Ltd.	GEMSS Medical Systems Co., Ltd.
	SID	950 ㎜	1000 ㎜
	Range of C-arm Rail Rotation	115° (90° / 25°)	135° (90° / 45°)
	Range of the Liner FR-arm Movement	200 ㎜	200 ㎜
	Range of the Linear T-arm Movement	500 ㎜	500 ㎜
	Range of Swing-arm Rotation	± 12.5°	± 12.5°
	Range of Stay-arm Rotation	360°	± 225°
Image Processing	Storage Capacity	Digital	HDD 500G
	Image Matrix size	5,000 Images	store more than 35,000 pictures (1 image is approximately 2MB)
	Monitor Size	17″	19″

		Predicate device	Proposed device
Collimator	Model name	KMC-950CM	KMC-950CMR1
	Manufacturer	COMED Medical Systems Co., Ltd.	GEMSS Medical Systems Co., Ltd.
	Collimator	Motor control / rotation	Motor control / rotation
	Power Requirements	DC 24V	DC 24V

GEMSS MEDICAL SYSTEMS CO., LTD., believes that the SPINEL 3G is substantially equivalent to the KMC-950 of United Radiology Systems, Inc. The SPINEL 3Gdescribed in this 510(k) has the similar intended use and similar technical and construction characteristics as the KMC-950 of United Radiology Systems, Inc.

7. Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to FDA recognized standards were performed. All test results were satisfactory. Applied standards are as follows:

- IEC60601-1:2005
- IEC60601-1-2:2007
- IEC60601-1-3:2008
- IEC60601-2-28:2010
- IEC60601-2-54:2009
- NEMA PS 3.1-3.20
- ISO14971:2012

And, EPRC regulation was satisfactory.

- 21CFR1020.32

In addition, FDA guidance was satisfactorily considered.

- Guidance for the Submissions of 510(k)s for Solid State X-ray Imaging Devices

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification GEMSS MEDICAL SYSTEMS CO., LTD. concludes that the SPINEL 3G is safe and effective and substantially equivalent to predicate devices as described herein.